REMARKS

I. Claim Status

Claims 1-6 and 8-20 are pending in the application and stand rejected. Claims 1-6 and 8-20 have been rejected under 35 U.S.C. § 112. Claims 1-6, and 8-20 have been rejected under 35 U.S.C. § 103.

II. Applicants' record of the substance of the interview

The Examiner conducted an interview with the undersigned attorney on August 29, 2002. Applicants' and their attorney thank the Examiner for her time in this interview. During the interview, the Examiner and Applicants' representative discussed the rejections under 35 U.S.C. § 112. The Examiner indicated that expressly reciting the description of the syngyna test described and required by the United States in the application would overcome the rejections. During the interview, Claim 1, the Moder et al. patent and the rejections under 35 U.S.C. § 103 were discussed. A representative sample of the invention of Claim 1 was shown to the Examiner. No claim amendments were presented or discussed. No Agreement was reached with respect the § 103 rejections. Further details regarding the interview are provided in the below detailed remarks regarding the specific outstanding rejections.

III. Rejections Under 35 U.S.C. § 112

Claims 1-6 and 8-20 have been rejected under 35 U.S.C. § 112, first paragraph, as supposedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. The Exmainer's position is essentially that § 112 requires an express description of the referenced test because it is a feature of the claimed invention.

Applicants disagree that Claims 1-6 and 8-20 are properly rejected under 35 U.S.C. § 112 as indicated in the Office Action. Indeed, as previously pointed out by the Applicants, the referenced syngyna test is well known in the industry, is required by the United States to be performed by all tampon manufacturers in the United States, and is expressly described by the United States in its own publication of Federal Regulations. Nevertheless, in an effort to focus on the remaining issues and to advance prosecution, Applicants have amended the specification to include an explicit description of the syngyna test corresponding to that published by the United States in the Code of Federal Regulations. This amendment is not new matter because it is merely making explicit what was already disclosed in the application (i.e. the details of a well-known industry test), which in any event was previously referred to in the application in a manner sufficient for one of skill in the art to identify it. During the interview conducted with the Examiner, the Examiner indicated that such an amendment would overcome the rejections under 35 U.S.C. § 112, first paragraph, and that entry of such an amendment would be proper. Therefore, Applicants are now presenting this amendment as suggested to advance prosecution. The Examiner is respectfully requested to withdraw the rejections under 35 U.S.C. § 112 and to allow the claims.

IV. Rejections Under 35 U.S.C. § 103

A. Rejections of Claims 1-5 over Moder et al.

Claims 1-5 are rejected under 35 U.S.C. § 103 as unpatentable over Moder et al. (U.S. Patent 5,986,165). It is the Applicants' position that these rejections are improper and should be withdrawn. Applicants arguments on this point are twofold: 1) the Office Action fails to make out a *prima facie* case of obviousness. Specifically, the Office Action does not point to specific and legally sufficient motivation or suggestion to modify the Moder et al. patent in the manner indicated. 2) Even if the Office Action has made out a proper *prima facie* case of obviousness, the Applicants have previously and again in this paper have provided and pointed to evidence which rebuts the *prima facie* case. This evidence has not been considered or sufficiently weighted in the Office Action.

1. The Prima Facie Case of Obviousness

The Moder et al. patent does not teach, either expressly or inherently, every feature of the invention claimed in Claim 1. For example, at a minimum, the Moder et al. patent does not disclose a tampon having a syngyna absorbent capacity of less than 6 grams packaged in a common package as a kit with a backup feminine protection product. Because each element of Claim 1 is not disclosed, the Moder et al. patent cannot anticipate Claim 1 under 35 U.S.C. § 102. As discussed in the Office Action, it is necessary to modify the teachings of the Moder et al. patent in order to arrive at the invention of Claim 1 and make out a *prima facie* case of obviousness under 35 U.S.C. § 103. Specifically, the teachings of Moder et al. must be modified to provide a tampon having an absorbency of less than 6 grams packaged in combination as a kit with a backup feminine protection product rather than providing tampons only having absorbencies greater than 6 grams and ranging up to 15 grams (which are the ranges disclosed in the Moder et al. patent).

A necessary requirement of a proper *prima facie* case of obviousness is that there must be a showing of the teaching or motivation to combine prior art references to arrive at the specific combination that was made by the application. In Re Sang Su Lee, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir 2002). In this case, the Office Action is not attempting to combine two references, but to modify the teachings of one primary reference. Because tampons having an absorbency of less than 6 grams are known in the art, this "modification" of the Moder et al. patent may also be thought of as a combination of the Moder et al. patent with such a prior art tampon having an absorbency of less than 6 grams. Applicants are not disputing that such a combination (or modification) would arrive at the claimed invention (one of the requirements of a *prima facie* case of obviousness). Rather, Applicants are disputing that the Office Action has put forth a proper showing of a suggestion or motivation to make the required combination (or modification) in the first place, which is another necessary requirement of a proper *prima facie* case of obviousness.

The Office Action does make a few attempts to show motivation to modify the teachings of Moder et al. For example, the Action notes that Moder does teach that the

absorbency of the tampon can vary. However, the entirety of the absorbency ranges disclosed in Moder et al. are "Regular," "Super," and "Super Plus," as these terms are defined by the FDA. These ranges correspond to greater than 6 grams up to and including 9 grams, greater than 9 grams up to and including 12 grams, and greater than 12 grams up to and including 15 grams all as measured by the syngyna test. 21 CFR § 801.430(e)(1). The reasoning of the Office Action is essentially that because Moder et al. discloses several possible absorbencies, including others not disclosed is obvious. In other words, the disclosure of three specific absorbency ranges provides the motivation to try other, undisclosed ranges. Another way of characterizing the reasoning of the Office Action is that the disclosure of some of the regulated absorbency ranges provides motivation to use others for the sake of completeness.

It is important to note that this is the **only** evidence pointed to in the Office Action for motivation to modify the Moder al. patent. The Office Action assumes that Moder et al. recognizes the advantages of making different absorbencies available based on the desire of the consumer. However, there is no evidence pointed to that there was previously **any** desire (by the consumer or otherwise) for the claimed kits having a tampon with an absorbency of less than 6 grams. The requirement of "motivation" or "desirability" of making a combination or modification to the prior art requires more than that the fact it **could** be done or that making the change would not be particularly challenging (in a technical sense). The showing of motivation to modify or combine must point to some expectation of success based upon the combination or modification. In other words, in this case the Office Action must point to a suggestion in the prior art which suggests that making the modification of the disclosed tampon would provide a reasonable expectation of success in providing the claimed feminine hygiene kit of Claim 1. The Office Action has failed to meet this burden.

Contrary to the arguments laid out in the Office Action, the United States Food & Drug Administration recognizes 6 categories of tampon absorbency, and not 4. The 6 recognized categories are: less than or equal to 6 grams (junior), greater than 6 grams up to and including 9 grams (regular), greater than 9 grams up to and including 12 grams (super), greater than 12 grams up to and including 15 grams (super plus), greater than 15 grams up to and including 18 grams (ultra), and greater than 18 grams (no term). 21 CFR § 801.430(e)(1). This means that Moder et al. at best discloses 3 of a possible 6 categories of absorbency, or only half. The most popular absorbency categories in the United States (in terms of consumer purchase) are the "regular," "super," and "super plus" categories. The Moder et al. reference omits any disclosure of ultra and junior absorbencies as well as of absorbencies greater than 18 grams. The disclosure of varying absorbency is taken in the Office Action that it would either be obvious to try other undisclosed ranges, or the motivation comes from a desire to offer all categories available (i.e. all those that could be offered). This reasoning, however, fails to demonstrate a reasonable expectation of success in accordance with the teachings of the present application. According to the reasoning of the Office Action it would be just as obvious to use an ultra absorbency tampon for the claimed feminine hygiene. The Office Action, however, points to no expectation of the success of the

particularly claimed combination (which still leaves 2 undisclosed absorbency categories to use the reasoning of the Office Action available) as being particularly suitable for a learner's kit as described in the instant application. The evidence relied upon in the Office Action points no more strongly to a motivation to modify the disclosed absorbency ranges to a lesser absorbency than it does to modify the disclosed ranges to a greater absorbency. Nor does the Office Action point to any evidence that one of skill in the art using only the teachings of the prior art (i.e. not applicants own disclosure) would recognize the particular suitability of a lesser absorbency tampon for inclusion in a learner's kit.

2. Evidence rebutting the prima facie case

Even assuming that the Examiner was correct in initially making the rejection of Claim 1 under 35 U.S.C. § 103 over Moder et al. as discussed above, Applicants have pointed to and put forth more than sufficient to rebut the *prima facie* case. Therefore, the rejections must now be withdrawn.

At the outset, Applicants point out that the Examiner is required to consider all proffered evidence of nonobviousness in making the final determination under 35 U.S.C. § 103. In Re Sang Su Lee, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir 2002). This evidence can come from (among other places) the specification and arguments or remarks made during prosecution. In Re Chu, 66 F.3d 1995; 36 U.S.P.Q.2d 1089 (Fed. Cir. 1995). MPEP 716.02(f). After evidence or argument is submitted in response to an obviousness rejection, patentability is determined on the totality of the record by a preponderance of the evidence with due consideration to persuasiveness of the argument. Id.

The Applicants have, in their specification, provided reasons why the particular combination claimed in Claim 1 would not have been suggested from a reading of the Moder et al. patent. This evidence is further supported below in this paper. All of this evidence must be considered. Upon such consideration, it should be apparent that this evidence outweighs any evidence provided in the Office Action that modification of the Moder et al. patent would have been obvious to one of ordinary skill in the art at the time the invention of Claim 1 was made. Additionally, the advantages associated with using a tampon having an absorbency of less than 6 grams in a feminine hygiene kit of the present invention are disclosed in the specification. These advantages are distinguished from the disadvantages associated with using previously known combinations or those unknown, but equally suggested (e.g. ultra absorbency) from the Office Action's reasoning in application of the Moder et al. patent.

Regular, Super, and Super Plus absorbency tampons are the most commercially popular sold in the United States. This explains their inclusion as examples in the Moder et al. patent. The Office Action assumes that using other absorbencies would be equally suitable for a feminine hygiene kit of the present invention. However, there is no evidence supporting this position. Indeed, at the time the invention of Claim 1 was made only

TAMPAX brand tampons were offered for sale in the United States in a junior absorbency and even these did not have widespread use among consumers. When given the opportunity to self-select for tampon trial, most users select regular or super absorbency, and typically these (usually along with super plus) are the only absorbencies found in many retail establishments.

The instant specification, beginning at the bottom of page 9, details many reasons why junior absorbency tampons are particularly suited for inclusion as a learner's kit and why such inclusion was contrary to common custom and thinking. The Applicants have detailed in the specification that low absorbency tampons for new users in particular are more comfortable and lead to a more positive using experience. The inclusion of a backup feminine hygiene product helps to allay fears associated with using a lower absorbency tampon. Additionally, the positioning of the resulting feminine hygiene kit as a learner's kit reinforces in the consumer's mind the particular desirability of the claimed combination for its intended and claimed purpose as a learner's kit. The Office Action puts forth **no evidence** tending to show that such insights would have been known or obvious to one of ordinary skill in the art at the time the invention of Claim 1 was made. Indeed as noted above, based solely on the evidence presented in the Office Action, one of skill in the art would be just as likely to use an ultra absorbency tampon as a modification of the teachings of Moder et al. There is simply not a preponderance of evidence that it would have been obvious to modify the Moder et al. reference in the manner claimed by Applicants as opposed to an equally available, but unclaimed manner. Nor may the Examiner ignore the evidence put forth in the specification that the Claimed kit is superior to one using other tampon absorbencies for the purposes described in Applicants' specficiation. The Examiner is not free to disregard the Applicants' disclosure in the specification that this particular combination has been found to offer particular advantage in the learner's kit context. In fact, the advantages which will be experienced by a novice user are detailed on Page 10 of the specification. The Examiner's position seems to be that unless quantitative comparative test data, is provided, that this evidence disclosing advantage of the claimed invention is insufficient.

A quantitative comparison of the claimed learner's kit to other possible combinations of tampons and backup feminine hygiene products is not required unless the Office Action puts forth evidence which outweighs Applicants teaching in the specification (and in this response) that the claimed combination works better for its indented purposes for the reasons described in the specification itself. The Office Action has put forth no evidence tending to support a contrary position, nor has the Office Action pointed to any evidence showing that one would be motivated to make this particular combination to the exclusion of other available possibilities. For all of these reasons, the invention of Claim 1 is nonobvious over the Moder al. patent and its rejection should be withdrawn. Because Claims 2-5 all depend from Claim 1, they are patentable over the Moder et al. patent for the same reasons given above with respect to Claim 1.

B. Rejection of Claims 1, 6, and 8-20 over Stravitz

Claims 1, 6, and 8-20 have been rejected under 35 U.S.C. § 103 as unpatantable over Stravitz (U.S. Patent 6,164,442). Stravitz merely discloses a multipart carrying case. The Stravitz patent teaches that numerous items can be placed in the case, such as tampons, baby wipes, mini-pads, and a mirror. The Office Action relies again on the Moder et al. patent for the notion that providing a tampon having an absorbency of less than 6 grams would have been obvious because Moder et al. teaches a variety of tampon absorbencies. The rejections over the Stravitz patent do not overcome any of the deficiencies discussed above with respect to the rejections over the Moder et al. patent. The Office Action uses Applicatns' own disclosure against them on page 6 of the Office Action. It is noted that a tampon having a syngyna absorbency of less than or equal to 6 grams is in the junior range according to the FDA regulations. 21 CFR § 801.430(e)(1). The table (and note 1 thereof) in the cited section of the regulations makes clear than "regular" absorbency starts at "greater than 6 grams." Therefore, even it were proper in the first instance to use the specification as evidence against the Applicants, the cited "evidence" does not stand for the factual position asserted in the Office Action. The rejections over the Stravitz patent do not supply any of the missing motivation or overcome the evidence discussed above with respect to the rejections over Moder et al. Therefore, these rejections under 35 U.S.C. § 103 are similarly improper and should be withdrawn.

C. Rejection of Claims 10-13 over Stravitz in further view of Morrow

Claims 10-13 have been rejected under 35 U.S.C. § 103 as unpatentable over Stravitz as previously applied in further view of Morrow (U.S. Patent 5,988,386). The Office Action, however, points to no evidence in the Morrow patent which supplies the missing teachings from either the Stravitz or Moder et al. patents. Therefore, these rejections fail to make out a proper *prima facie* case of obviousness, or even if such case has been made do not overcome the evidence cited which successfully rebut it. Therefore, these rejections under 35 U.S.C. § 103 should be withdrawn.

SUMMARY

Attached hereto is a marked-up version of the changes made to the application by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

All of the relevant rejections in the Office Action have been discussed.

Copies of all cases, regulations, and other legal authority cited have been provided with this response for the Examiner's convenience.

In light of the discussions contained herein, Applicants respectfully request reconsideration of the rejections and their withdrawal, and that all of the claims be allowed.

Issuance of a Notice of Allowance at an early date is respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

The paragraph beginning on Page 9, line 22 has been amended as follows:

All of the absorbency ranges given herein are those as measured by the [syngina] sygyna test as mandated by the FDA, a description of which is reproduced in the "Test Methods" section, below. Preferably, the tampon 24 of the present invention is of the "junior" absorbency type. This absorbency level is also sometimes referred to as "lites" or "light absorbency." A suitable tampon of this type is manufactured and sold by the Procter & Gamble Company of Cincinnati, Ohio as TAMPAX LITES. Such a tampon may preferably have a basis weight of about 438 g/m^2, and be constructed from a rectangular absorbent pad comprising 100% cotton. The pad may have an initial length of about 76 mm, and an initial width of about 45 mm prior to compression. The absorbent pad is compressed to its final form, such as that shown in FIG. 4 by temperature and pressure using techniques that are well known in the art.

The Test Method section inserted beginning on Page 15, after line 20 is a new section.